K010336

FEB 1 6 2001

GE Medical Systems
General Electric Company
P O Box 414 Milwaukee, WI 53201

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Submitter Larry A. Kroger, Ph.D.
Senior Regulatory Program Manager
Telephone: (414) 544-3894, FAX: (262) 544-3863
Date Prepared: November 30th, 2000

PRODUCT IDENTIFICATION

Name: Advantage Windows CT/PET Fusion

Classification Name: Accessory to Computed Tomography System

Manufacturer : General Electric Medical Systems
283, rue de la Miniere
78533 Buc Cedex, FRANCE

Distributor: General Electric Medical Systems, Milwaukee, WI

Marketed Devices The CT/PET Fusion is substantially equivalent to the device listed below:

Model:	Advantage Windows Fusion (CT/MR Fusion)
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K983256

Device Description:
The GEMS Advantage Windows CT/PET Fusion software package is an option on Advantage Windows that provides easy comparison of three dimensional (3D) images from Computed Tomography (CT) and Position Emission Tomography (PET) or GEMS Hawkeye Single Photon Emission Tomography (SPECT). It allows 3D registration between two volumetric acquisitions, which may come from different acquisition modalities, producing fusion of anatomical and functional images.

Indications for Use :
Advantage Windows CT/PET Fusion provides an easy means for comparison of three dimensional (3D) images from Computed Tomography (CT: providing anatomical imaging) and Emission Tomography (PET or SPECT: providing functional imaging). It allows registration between two

volumetric acquisitions, which may come from different acquisition modalities (CT and PET/SPECT), for use in diagnostic radiology or therapy planning.

Comparison with Predicate:
The Advantage Windows CT/PET Fusion option allows merged 3D registration of anatomical images from CT with functional images from PET/SPECT. The functional features of this package are substantially equivalent to that of the following device:

Device Name	FDA Clearance Number
Advantage Windows Fusion	K983256

Adverse Effects on Health :
The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:
The Advantage Windows CT/PET Fusion does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the Advantage Windows CT/PET Fusion to be equivalent to those of Advantage Windows (CT/MR) Fusion (K983256).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 6 2001

GE Medical Systems, Inc.
C/O Reiner Krumme
TUV Rheinland of North America, Inc.
12 Commerce Road
NEWTON CT 06470

Re: K010336
Advantage Windows CT/PET Fusion
Dated: February 2, 2001
Received: February 5, 2001
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INTENDED USE

510(k) Number (if known): K010336

Device name: Advantage Windows CT/PET Fusion

Indication For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use _____
(Per 21 CFR 801.109)

David C. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010336